

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DMGE042PWO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2005/002196	International filing date (<i>day/month/year</i>) 02.03.2005	Priority date (<i>day/month/year</i>) 02.03.2004
International Patent Classification (IPC) or national classification and IPC A61K6/083		
Applicant ERNST MÜHLBAUER GMBH & CO. KG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of _____ sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>7</u> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-41 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-26 _____ received by this Authority on 02.01.2006 with telefax
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☒ the claims, nos. 27 _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 15

because:

☒ the said international application, or the said claims Nos. 15

relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 15 relates to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv).

Consequently, no expert opinion has been established in respect of the industrial applicability of the subject matter of said claim (PCT Article 34(4)(a)(i)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-26</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u>1-26</u>	YES
	Claims	<u></u>	NO
Industrial applicability (IA)	Claims	<u>1-14, 16-26</u>	YES
	Claims	<u></u>	NO
2. Citations and explanations (Rule 70.7)			
<p>The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claim 15 in its present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.</p> <p>Reference is made to the following documents:</p> <p>D1: WO 02/092022 A (KERR CORP) 21 November 2002 (2002-11-21) mentioned in the application</p> <p>D2: US-A-6 121 344 (KOBASHIGAWA ALVIN I ET AL) 19 September 2000 (2000-09-19)</p> <p>D3: EP-A-1 149 573 (SHOFU KK) 31 October 2001 (2001-10-31)</p> <p>D4: EP-A-0 530 926 (KANEBO LTD; MITSUBISHI CHEM IND (JP) 10 March 1993 (1993-03-10)</p> <p>D5: DE 100 42 050 A (DEGUSSA; KARLSRUHE FORSCHZENT (DE)) 14 March 2002 (2002-03-14)</p> <p>D6: PATENT ABSTRACTS OF JAPAN vol. 1997, no. 11, 28 November 1997 (1997-11-28) & JP 09 194674 A (SAN MEDICAL KK) 29 July 1997 (1997-07-29)</p> <p>D7: PATENT ABSTRACTS OF JAPAN vol. 1996, no. 10, 31 October 1996 (1996-10-31) & JP 08 143747 A (SAN</p>			

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>MEDICAL KK) 4 June 1996 (1996-06-04)</p> <p>D8: EP-A-0 648 484 (HERAEUS KULZER GMBH) 19 April 1995 (1995-04-19)</p> <p>D9: DE 196 17 931 A (IVOCLAR AG) 6 November 1997 (1997-11-06)</p> <p>Claim 1 claims a filled and polymerizable dental material characterized in that it comprises:</p> <p>a) an organic binder</p> <p>b) a nanoscale filler which exhibits the following features:</p> <ul style="list-style-type: none">- at least 50% by weight of the nanoparticles have a particle diameter of less than 200 nm,- at least 20% of the number of nanoparticles are aggregated particles,- <u>the nanoscale filler has undergone organic surface modification</u> <p>c) at least one inorganic and/or organic filler selected from the group consisting of a ground filler with an average particle size between 0.2-50 µm and a spherical filler with an average particle size between 0.1-50 µm.</p> <p>Document D1 (or D2 or D4 or D9) is regarded as the closest prior art to the subject matter of claims 1, 15 and 16. These documents disclose the production of a filled and polymerizable dental material using a nanoscale filler. One difference from the present invention is that the nanoscale filler particles of the dental materials according to D1, D2, D4 and D9 are not in agglomerated and/or aggregated form.</p> <p>The subject matter of claims 1, 15 and 16 is thus novel (PCT Article 33(2)).</p> <p>The problem addressed by the present invention can therefore be considered that of providing filled and polymerizable dental materials, and a process for their production, which</p>

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	<p>have good mechanical properties such as good flow behaviour in the processing phase and compressive strengths and abrasion resistance in the cured state.</p> <p>The solution proposed for this problem in claims 1, 15 and 16 of the present application involves an inventive step (PCT Article 33(3)), for the following reasons:</p> <p>The invention has realized that a dental material with good mechanical properties can be obtained even starting from fillers in which nanoscale primary particles are agglomerated and/or aggregated if these aggregated or agglomerated fillers initially undergo organic surface modification and are subsequently incorporated into an organic binder, the incorporation breaking down agglomerates and aggregates to such an extent that at least 50% by weight of the nanoparticles have a particle diameter of less than 200 nm. Documents D3 and D5-D8 disclose merely fillers or filler aggregates in the micrometre range. A person skilled in the art would not have considered these fillers because he wished to produce a dental material in the nanometre range.</p> <p>Claims 2-14 and 17-26 are dependent on claims 1 and 16 and thus likewise meet the PCT requirements for novelty and inventive step.</p>